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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,353	07/30/2001	Svetlana Alexadrovna Morenkova	P67002US0	1986

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EXAMINER	
WINSTON, RANDALL O	
ART UNIT	PAPER NUMBER
1654	10

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/890,353	Applicant(s) Morenkova
	Examiner Randall Winston	Art Unit 1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *19-31* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *19-31* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Acknowledgment is made of receipt and entry of the amendment filed April 17, 2003.

Claims 19-31 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-31 are rejected under 35U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is render vague and indefinite for the broad term "linking agent." One of ordinary skill in the art would not know how to delineate the metes and bounds of the broad term "linking agent." (Is the "linking agent" other compounds or just glutarite dialdehyde? (also see, e.g. claim 25 rejection below)).

Claim 19 is render vague and indefinite for the phrase "linking agent in proportion, in mass%." One of ordinary skill in the art would not know how to interpret the metes and bounds of the above phrase. It is also unclear from the claim language of what ratio or proportion of each

active ingredient is in relationship to one another (i.e. the ratio of the linking agent/insulin/erythrocytes to one another).

Claim 25 is render vague and indefinite for the phrase "further comprising glutarite dialdehyde." One of ordinary skill in the art would not know how to interpret the metes and bounds of the above phrase. (Does the insulin-containing medicine include both a "linking agent" and glutarite dialdehyde?)

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth.

Please note that the language of the claims must make it clear what subject matter the claims encompass to adequately delineate their "metes and bounds." See, e.g., the following decisions. In re Hammack, 427 F.2d. 1378, 1382, 166 USPQ 204, 208 (CCPA 1970); In re Venezia 530 F 2d. 956, 958, 189 USPQ 149, 151 (CCPA 1976); In re Goffe, 526 F 2d. 1393, 1397, 188 USPQ 131, 135 (CCPA 1975); In re Watson, 517 F 2d. 465, 477, 186 USPQ 11, 20 (CCPA 1975); In re Knowlton 481 F 2d. 1357, 1366, 178 USPA 486, 492 (CCPA 1973). The courts have also indicated that before claimed subject matter can properly be compared to the prior art, it is essential to know what the claims do in fact over.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19-31 as amended stand rejected under 35 U.S.C. 103(a) as being unpatentable over Morenkova (see Derwent abstract, ACC-NO: 1997-041104) in view of Cho et al. (US 5,665,700).

Applicant submits that Morenkova discloses 0.15-0.25% of glutarite dialdehyde in the final concentration of the insulin preparation. The present invention as claimed comprises 0.05-0.15% of the linking agent in the final composition. Therefore, the difference in the concentration of the linking agents are significant because lower concentrations are desire because of reduced toxicity. Applicant's argument, however, is not found persuasive because as stated in the above 112, second rejection, it is unclear from the claim language of claim 19 of what is a "linking agent" and of what ratio or proportion of each active ingredient is in relationship to one another in claim 19 (i.e. the ratio of the linking agent/insulin/erythrocytes to one another). Therefore, although very unclear as drafted, applicant apparently claims an insulin-containing medicine for peroral use comprising a linking agent (i.e. glutarite dialdehyde (?)), insulin (i.e. of a particular form), erythrocytes and an auxiliary substance (i.e. gelatin) whereas the above active ingredients are of various ratios and/or proportions (?).

Morenkova teaches the claimed invention' insulin-containing medicine for peroral use comprising a linking agent (i.e. glutarite dialdehyde), insulin, and erythrocytes (see, e.g. abstract). Morenkova does not teach gelatin contained within an insulin-containing medicine.

Cho et al. beneficially teach gelatin contained within an insulin preparation for packing purposes (see, e.g. column 13 line 2 and column 17 lines 19-22).

It would have been obvious to one of ordinary skilled in the art at the time the claimed invention was made to modify Morenkova to include gelatin as beneficially disclosed by Cho et al. for packing purposes of an insulin-containing medicine. Thus, the adjustment of these and other conventional working conditions (e.g. the insulin form and/or active ingredients amounts/ranges), is deemed merely a matter of judicial selection and routine optimization which is well within the purview of the skilled artisan. Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Please note (claims 23, 24 and 26-31 are rejected) because the patentability of a product does not depend upon the method of production. If the product in a product-by-process claim is the same as obvious from a product of the prior art, then the claim is unpatentable even though the prior art product was made a different process. (see, e.g. MPEP 2113).

Claims 19-31 are not allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is (703) 305-0404. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

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LEON B. LANKFORD, JR.
PRIMARY EXAMINER